Remarks

1) Applicant thanks the Examiner for his office action and hopes that this response will further the understanding of applicant's invention.

2) Applicant respectfully directs the Office's attention to the fact that the present application claims priority under 35 U.S.C. §119 to PCT application No. PCT/US05/05536, filed February 15, 2005. Applicant respectfully requests that the Office will acknowledge that applicant met all the requirements for this claim of priority.

3) Applicant provides herewith an amended drawing sheet in which Fig. 2 was amended to show the integral tension element, as required by the Examiner. Applicant respectfully submits that the amendment to the drawing merely brought the drawing into concordance with the specification and no new matter was introduced.

4) Claims 1-26 are pending in the application and stand rejected. Claims 1, 4-7, 10, 13, 17 and 18 are hereby amended.

5) Applicant thanks the Examiner for noticing the informalities in claim 18. Applicant amended claim 18 and several others to correct minor grammatical and typographical mistakes.

6) MPEP 707.07(d) requires: *A plurality of claims should never be grouped together in a common rejection, unless that rejection is equally applicable to all claims in the group.* The Office Action grouped together rejections of claims, and failed to specifically point out where the elements and limitations of **EACH REJECTED CLAIM** are found in the cited references as required by the MPEP. Applicant therefore respectfully demands that the Examiner will provide an Office Action which provides a clear ground for rejecting EACH CLAIM as dictated by the MPEP..

7) Due to the failure detailed above, applicant could not decipher which portion of the Office Action relates to which claim, and the grounds or logic for most of the rejections. Lacking the specific grounds for rejection for each claim, applicant is unable to orderly respond to all points. This should not be construed as an

acceptance or acquiescence of the Examiner's position by applicant. Applicant reserves the right to respond to all rejections and objections once those are made properly.

8) The present invention relates to a hinged orthosis comprising of at least two hinged shell parts. The hinge design comprises a tensor and a compression element, whereby the shell parts are coupled by the tensor element, while simultaneously applying pressure to compression element, to provide lift assist to a patient's jointed extremity. This operation of tensioning by the tensor and the oppositely compressing the compression element allows finely tuned control of the forces applied to the patient's limb. Thus the lift support is achieved by compression forces, and opposing tension forces. Furthermore, to provide a smooth transition between the two hinged parts, the invention claimed in claims 1-17 offers a tensor having a flat area substantially co-planer to the inner surface of the orthosis adjacent to the tensor.

9) The Office rejected claims 1-2, 4-9, 11-13, and 17-22 under 35 U.S.C. §102(b) as being anticipated by McShane et al. (US Patent 5,685,811). The McShane patent relates to a universal muscular conditioning device, which provide for the placement of two bidirectionally acting, frictionally resistant elements on opposite sides of a joint, in order to require a wearer of the device(s) to provide additional muscular exertion against the frictional resistance and thereby build muscular and joint strength. The disclosed embodiment includes a wrap (10) which may be adjustably secured about the joint(s) or limb(s). The wrap includes a plurality of pockets or sleeves, into which two of the frictionally resistive elements may be placed opposite one another, to the lateral and medial sides of the joint and essentially coaxial with the joint center. (McShane abstract). The McShane device differs from the present invention, as claimed, in several substantial ways, some of which are detailed below.

10) The Office equated the orthosis hinged parts of the present invention, with one type of a disclosed resistive element, a geared device in which the gear sectors are formed of a resilient material and are adjustably compressed together to vary the friction

therebetween. Applicant respectfully submits that the Office misinterpreted the claim language and the nature of the McShane disclosure.

11) Independent claims 1 and 18 as well as their dependent claims, relates to an ORTHOSIS having a first and a second hinged parts. The Office equated a wrap (10), to an articulated orthosis. According to the American Heritage Dictionary, a wrap may properly be considered as a blanket or wrapping or a wrapper, such as to wrap an object. Articulation requires a joint joining at least two parts. Thus applicant respectfully submits that equating the McShane wrap to an articulated orthosis is not supported by any reasonable interpretation as McShane does not disclose any articulation or even two separate orthosis parts as originally claimed.

12) Moreover, applicant respectfully submits that even at its broadest reasonable interpretation, one may not reasonably equate a resistive element that happens to be a part of an orthosis, with the orthosis itself. In order to more distinctly clarify the difference, applicant amended the claims to more clearly show that the hinged parts relate to the orthosis shell, and not to a resistive element. As reasonable - broad or narrow – interpretation of the claim language in view of the specifications clearly points to that fact, the amendment should not be considered narrowing the claims in any way.

13) To further buttress the assertion that the equating the McShane resistive elements with the claimed orthosis parts is incorrect given any reasonable interpretation, applicant points out that the principle of operation differs radically between the McShane resistive elements and the present invention. McShane clearly states that his device operates on the basis of frictional forces (e.g., abstract), while the present invention utilizes the combination of tension and counter-acting compression forces, while rotational friction may be merely a parasitic side-effect of these cooperating forces. Thus, it is clear that McShane's resistive element shown in Fig. 4 does not properly equate to the two hinged parts as claimed.

14) The Office alleged that the claimed first and second compression surfaces, are disclosed by Fig. 4 of the McShane's patent. In col. 8, ll. 24-39 McShane describes Fig. 4 as follows:

> *FIG. 4 provides a perspective view of an alternative embodiment of an element 74, wherein the upper and lower arms 76/78 each respectively include a first gear sector 80 and matingly engaged second gear sector 82, which sectors 80/82 comprise the* ***friction joint ends*** *of the two arms 76/78. The gear sectors 80/82 are compressed together by an elongate connector 84 extending across the two sectors and securing the two friction joint ends and sectors 80/82 together. Each of the arms respectively includes a first and a second pivot 86/88 thereon, with the connector 84 being placed in tension between the pivots 86/88 to urge the sectors 80/82 compressibly together. By forming the gear sectors 80/82 of a compressible, resilient material (neoprene, etc.), they will be distorted when compressed, thereby providing a frictional resistance to their meshing as the arms 76/78 move arcuately relative to one another.* (Emphasis added)

The applicant submits that Fig. 4 clearly does not disclose **compression surfaces** which are **coupled to the first and second parts respectively**, and **located to transmit forces** to the compression element which is **disposed therebetween**. Applicant therefore requests that if the rejection is upheld, that the Office will kindly specifically point out those elements and show how they fulfill the claimed limitations.

15) As far as the compression surfaces as a whole, applicant points out that McShane did not use this term, and applicant failed to find in Fig. 4 any surfaces that can even remotely fit the compression surfaces of the present invention, given the broadest possible interpretation. Applicant therefore respectfully requests that the Office will specifically point out where such compression surface are found.

16) The Office equated the claimed tension element to the connector 84 in the McShane patent. However applicant claims 1-17 further requires that the tension element should have 'at least one generally flat outer surface which is substantially co-planar to the inner surface of the orthosis adjacent to the tension element'. Connector 84 is clearly shown to be round, and clearly having no co-planar surfaces with any surface that may be considered the inner surface of the orthosis. Applicant failed to find any explicit or implicit disclosure of these claimed features in the McShane patent, neither did the office provided such reference. While references to this feature may be found in various places in the present application, paragraph 0043 describes in detail some advantages provided by such feature in the case of a foot orthosis. Neither the compression surfaces, nor the tensor having a generally flat surface co-planar with the inner surface of the orthosis, are disclosed or even hinted of by any of the references. Thus applicant respectfully submits that the Office failed to establish a *prima facia* case for lack of novelty.

17) Furthermore, the Office asserted that the tension element 84, and gear sectors (80, 82) are "*fully capable of being disposed at least partially between within the chamber (28).*" Applicant respectfully disagrees. Drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. *In re Aslanian,* 590 F.2d 911, 200 USPQ 500 (CCPA 1979) Applicant respectfully submits that while examining Fig. 4, the person skilled in the art will see the upper and lower arms being disposed within the sleeve 28, as shown in as shown for example in Figs 1 and 6, however the drawings will also suggest that the friction mechanism will not be disposed within the sleeve 28 but in-between the individual aligned upper and lower sleeves of sleeve groups 20/22 or 24/26. If one was to place any gear sector within the sleeves, the sleeves will be so big as to allow the arms 76-78 to move freely, thus defeating the operation of the McShane device. Applicant respectfully requests that the Office will withdraw the rejection of claims 1-17, or that it will specifically point out and explain the reasoning for the impermissible extension of the disclosure provided by the drawing, so as to meet its obligation under *in re alsanian.*

18) Applicant submits that for all the reasons stated herein, the Office erred in equating the claimed hinged parts with upper and lower arms 76, 78, as well as equating the claimed compression element with the gear sectors 80 and 82, and connector 84 with the claimed tension element. However to improve clarity in this response, applicant may apparently accept such equations, to avoid repetition of this argument and to ease understanding of applicant's argument. Such usage should not be construed as implicit or explicit admission of agreement with the Office's assertion.

19) In order to provide as complete a response as possible, applicant attempted to guess which grounds the Office used to reject which claim, and to respond to the best of his understanding. If applicant's interpretation is inaccurate, the Office is hereby again respectfully requested to more specifically, separately, and individually, point out the reasoning for the rejection of each rejected claims.

20) Regarding claim 4, to the best understanding of the applicant, the office asserted that the angel between the first and second hinged parts (76, 78) is inherently varied by the dimensions of the compression element (80, 28) [sic] because it is directly between the first and second hinged parts (76,78) in the unloaded position. Applicant respectfully disagrees, since it is clear that changing the gear dimensions will not by itself change the ANGLE between the parts 76 and 78 which the office equated with the hinged parts, but the DISTANCE therebetween. Furthermore, the claim relates to changing the dimensions of at least a single element. Changing the dimensions of only a single element of the two shown will make the McShane invention inoperable as the gearing will not mesh as required by the McShane disclosure (col. 8, ll. 24-39).

21) Regarding claims 7-9 and 11, the Office asserted that a chamber is interpreted to be an enclosed space or compartment. However applicant fails to see, and therefore respectfully asks that the Office will clarify, how an ENCLOSED space may be defined by open distances between the hinged parts and the tension elements, wherein the wrap is proximal to hinged parts and with no walls, enclosure or anything that may be even remotely considered to enclose the space between the tension element 84 and upper and lower arms 76, 68. Failing a clear explanation and showing, applicant submits that the Office impermissibly provided an extremely overbroad interpretation of the term "ENCLOSED SPACE", and that the tension element 84 having no apparent enclosure,

may NOT serve to define the boundary of the non-existent chamber in the McShane, as claimed by the Office's interpretation.

22) Claim 18 is directed to an articulated orthosis comprising *inter alia* of a plurality of retaining walls defining a chamber, a compression element and a tension element disposed at least partially within the chamber, wherein the tension element is disposed between the compression element and at least one of the chamber walls. For the reasons discussed *supra*, applicant respectfully submits that the Office failed to establish a *prima-facia* case of lack of novelty as the references do not disclose neither a tension element nor a compression element disposed at least partially within the chamber. Furthermore, applicant respectfully submits that the office failed to show any teachings where the tension element is disposed between the compression element and any wall of the chamber.

23) Claims 3, 10, 15-16, and 23-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over McShane et al.

24) Regarding claim 10, which stand rejected under 35 U.S.C. §103(a) under McShane in view of Bartlet (US patent 6,074,355). Despite repeated reading of the first paragraph of page 6 of the Office Action, as well as anywhere else therein, the undersigned failed to understand the grounds on which the Office rejected this claims. In the case of claim 10, there is not as much as a mention of the claimed limitation that the second block is to be compressed only after compression has been applied to the first block, nor is there any connection between the claim and the alleged evidence provided by Bartlett. Bartlet discusses using varying composition of a SINGLE extension cushion. Nowhere in the cited reference was applicant able to find teachings, hint, or even remote suggestion, to the claimed features of having two compression elements of differing modulus of elasticity, cooperating so as to apply the compression to the second element only after compression was applied to the first element. Applicant failed to find any hint in his own claim 10 of specific ranges of modulus of elasticity, and fails to understand the relevance of the holding declared by the Office. Therefore applicant respectfully requests that the rejection will be withdrawn or that the Office will provide a clear and organized showing of the specific elements, limitations and features that can provide a proper basis to reject claim 10.

25) Responding to the en-mass rejection of separate and unique claims, applicant will hereby point out but a few of the erroneous statements made by the Office. However, as the Office failed to show to which claim an erroneous statement relates, applicant is unable to relate those errors to specific claims:

- On page 4, ll. 4 the Office asserted that McShane discloses the tension element (84) disposed between the compression element (80,82) and the chamber walls (38). While it may be possible to place the tension element inside the digit place in the glove, applicant failed to see any hint or suggestion, nor did the office provided any reason why a person having any skill in the art would attempt to do so.
- On page 4, ll. 6 the Office asserted that the tension element (84) is retained in place by forces applied by the compression element (80-82). Applicant respectfully submits that Fig. 4 shows the tension element being supported by pivots 86 and 88, and is not any way held in place by any forces applied by the compression elements.
- On page 4, ll. 7-9 the Office asserted that the Mcshane discloses a support (92) that interacts with the compression element to retain the compression element in place. Applicant submits that nothing stated in Col. 8 ll. 45-50, nor anything in Fig. 4 hints of holding the tension element in place by the wing screw element (92). All that McShane states is that the wing screw may be used to adjust the tension of the connector between the two arms.
- On page 4, ll. 18-19 the Office asserted that compression surfaces (Fig. 4) are integral to the hinged parts (76,78). As stated above applicant failed to find any structure that would fit the compression surfaces. Applicant therefore respectfully requests that the Office will specifically point out where such compression surface are found, and how they are integral to the hinged parts.
- On page 6, ll. 4-12, the office admitted that McShane fails to disclose a second compression element having higher modulus of elasticity than the first compression element. The Office further involved a certain range of bending stiffness. Applicant is uncertain about the connection between the bending stiffness range and the different modulus of elasticity of the two elements. Moreover, the office stated that: *"it would have been obvious to one skilled in*

the art at the time the invention was made to the first compression element have a higher modulus of elasticity than the first compression element".
Since this statement constitutes a contradiction in terms, applicant assumes that the Office meant that it would be obvious for the skilled in the art to have a second compression element having a higher modulus of elasticity than the first compression element.
The Office did not support its assertion by any documentary evidence. It therefore follows that despite lack of statement thereto, the Office took official notice that the combination of a first and a second compression elements having differing modulus of elasticity is common knowledge in the art.
In *re Ahlert, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970)*, the court noted that notice of facts beyond the record which may be taken by the examiner must be *"capable of such instant and unquestionable demonstration as to defy dispute"*. Applicant disputes the notice of facts beyond the record, and submits that such notice has not been shown capable of the required instant and unquestionable demonstration.
Applicant traverses the factual assertion taken by the Examiner, as utilizing a first and a second compression elements wherein the second compression element has a higher modulus of elasticity than the first compression element. Applicant states that the factual assertion is untrue, that the Examiner did not properly officially noticed, and that the finding is not properly based upon common knowledge. Applicant specifically asks that the Examiner will support the finding with adequate evidence, or that the assertion will be withdrawn.

- Moreover, on page 6 ll. 14-18 the Office asserted that Bartlett *"provides evidence that is was known in the art to vary the size or composition ... of the compressible element in order to meet the needs of the user. The same principles would have to be applied to the* ***tension element*** *in order for the two elements to operate properly together without one being overly stronger*

the other". The applicant assumes that the Office meant to relate to a compression element rather than to a tension element, but submits that the Office thereby contradicts its own earlier statement that it would be obvious to use two compression elements having differing modulus of elasticity, as by doing so one element would inherently be overly stronger than the other.

26) Applicant respectfully requests that the Office will recognize and correct the above glaring errors, and withdraw any rejection stemming thereof.

27) Should the Examiner find any deficiency in this amendment or in the application, or should the Examiner believe for any reason, that a conversation with applicant's agent may further the allowance and issuance of this application, the Examiner is kindly requested to contact Shalom Wertsberger at telephone (207) 799-9733.

28) Applicant has made a good faith effort to address each and every point made by the Examiner, in view of the many shortcomings of the Office Action. Applicant amended the claims and the drawings, in order to place the application in condition for allowance. In light of the showing and all other reasons stated above, applicant believes that the rejections and objections presented by the Examiner in the office action mailed to applicant Mar 24, 2008 were overcome. Applicant therefore submits that the claims as amended are in condition for allowance. Reconsideration and withdrawal of all the rejections and objections, and issue of a notice of allowance on all pending claims is respectfully solicited.

Respectfully submitted

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